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JUL 16 2009

SECTION 5: 510(k) Summary

Hill Laboratories, Inc. requests that the attached "summary" for the Aklarus Phototherapy System be distributed upon request under the Freedom of Information Act. This report is a summary of the information presented in this 510(k) submission.

510(k) SUMMARY

For

Hill Laboratories

Aklarus Phototherapy System

1. Submitter's Name and Address

Submitter's Name:	Hill Laboratories
Address:	3 Bacton Hill Rd
City, State, and Zip:	Frazer, PA 19355

2. Contact Person

Name:	Brady Aller
Title:	Therapeutic Product Manager
Telephone:	(610) 644-2867
Facsimile:	(610) 647-6297
E-mail:	bradyaller@hilllabs.com

3, Manufacturing Facility Address

Manufacturer:	Hill Laboratories
Address:	3 Bacton Hill Rd
City, State, and ZIP:	Frazer, PA 19355

4. Establishment Registration Number

Establishment Registration Number:	2510425

5. Reason for Submission

New Device

6. Date of Summary Preparation

September 6, 2008

7. Device Details

Proprietary or Trade Name:	Aklarus Phototherapy System

Common Name	Class	ProCode	CFR
Infrared lamp	2	ILY	890.5500
Laser surgical instrument for use in general and plastic surgery and in dermatology	2	GEX	878.4810

8. Classification Name

Lamp, Infrared, Therapeutic Heating
Laser Instrument, Surgical, Powered

9. Device Classification Panel

Physical Medicine

10. Indications for Use

The Aklarus Blue (420nm +/-10nm), is generally indicated to treat dermatological conditions and specifically indicated to treat moderate inflammatory acne vulgaris.

The Aklarus combination of Red (628nm +/-10nm) and Blue (420nm +/-10nm) is intended to emit energy in the red, blue regions of the spectrum to treat dermatological conditions, specifically indicated to treat mild to moderate acne vulgaris.

The Aklarus Anti-Aging Red (628nm +/-10nm) and Anti-Aging Infrared (880nm +/-10nm) Combination is intended to emit energy in the red and infra-red region of the spectrum for use in dermatology for the treatment of periorbital wrinkles.

The Aklarus Infrared (880nm +/-10nm) is intended to emit energy in the IR spectrum to provide topical heating for the purpose of elevating tissue temperature; for the temporary relief of minor muscle and joint pain, arthritis and muscle spasm; relieving stiffness; promoting the relaxation of muscle tissue; and to temporarily increase local blood circulation where applied.

11. Primary Predicate Device

510(k) Number	*Trade or Proprietary or Model Name*	*Manufacturer*	*Class*
K060792	Illumimed	Hill Laboratories	2

12. Additional Predicates

1	K050216	1	Omnilux Revive & Omnilux Plus Combo	1	Photo Therapeutics Limited
2	K041103	2	AcneLift	2	Inner Act, LLC

3	K030883	3	Omnilux Blue	3	Photo Therapeutics Limited
4	K043317	4	Omnilux Plus	4	Photo Therapeutics Limited

13. Conclusion

The proposed Aklarus Phototherapy System when used as directed in the operator's manual presents no new safety or effectiveness concerns and is Substantially Equivalent to the predicate devices listed in this section.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 16 2009

Hill Labortories, Co.
% Mr. Brady Aller
Therapeutic Product Manager
3 Bacton Hill Road
Frazer, Pennsylvania 19355

Re: K083183
Trade/Device Name: Aklarus Phototherapy System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX, ILY
Dated: July 10, 2009
Received: July 14, 2009

Dear Mr. Aller:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

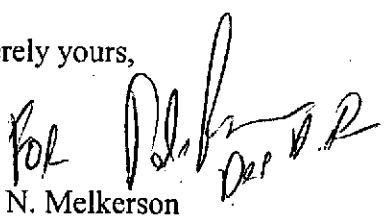
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use

510(k) Number (if known): K083183

Device Name: Aklarus Phototherapy System

Indications for Use:

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The Aklarus combination of Red (628nm +/-10nm) and Blue (420nm +/-10nm) is intended to emit energy in the red, blue regions of the spectrum to treat dermatological conditions, specifically indicated to treat mild to moderate acne vulgaris.

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The Aklarus Infrared (880nm +/-10nm) is intended to emit energy in the IR spectrum to provide topical heating for the purpose of elevating tissue temperature; for the temporary relief of minor muscle and joint pain, arthritis and muscle spasm; relieving stiffness; promoting the relaxation of muscle tissue; and to temporarily increase local blood circulation where applied.

Prescription Use ___X___ AND/ Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) OR (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R P Ogden for mkm

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K083183